K111209
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GE Healthcare

Integrated Innova - s5i system option - 510(k) Premarket Notification

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: April 27th, 2011	
Submitter:	GE HEALTHCARE GE Medical Systems SCS 283, rue de la minière 78530 BUC FRANCE
Primary Contact Person:	Fayçal KHERRA Regulatory Affairs Leader GE Medical Systems SCS 283, rue de la minière 78530 BUC FRANCE T: +33 1 30 70 40 82 Email: Faycal.kherra@ge.com
Secondary Contact Person:	Carol Alloian Regulatory Affairs Leader GE Healthcare, QARA Regions - Americas 9900 W innovation drive Wauwatosa, WI, USA, 53226-4856 T: (847) 244-8327 F: (847) 589-8524 Email: carol.alloian@ge.com
Device/Trade Name:	Integrated Innova - s5i system option (Formerly known as Innova System with IVUS Option)
Common/Usual Name:	Integrated Innova - s5i system option (Formerly known as Innova System with IVUS Option)
Classification Names: Product Code:	IZI : SYSTEM, X-RAY, ANGIOGRAPHIC MQB : SOLID STATE X-RAY IMAGER (FLAT PANEL/DIGITAL IMAGER)
Predicate Device(s):	K061163 : INNOVA x1x1[IQ] & X100[IQ] systems with IVUS option
Device Description:	The integrated INNOVA - s5i system option provides enhanced connectivity with Volcano's intravascular imaging and pressure system.

Intended Use:	The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. The Integrated Innova - s5i system option is indicated for use in conjunction with single plane and biplane angiographic X-ray systems. The Integrated Innova - s5i system option simplifies the clinical workflow associated with the use of Volcano s5i systems by: (1) automatically synchronizing the patient demographic and medical exam information (patient name, date of birth, etc.) from angiographic X-ray systems with Volcano s5i systems, (2) providing a remote access to commonly used Volcano s5i system functions from the angiographic X-ray systems user interface, (3) displaying the Volcano s5i systems output on the monitor display solutions of the angiographic X-ray systems.
Technology:	The integrated Innova - s5i system option employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The integrated Innova - s5i system option complies with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Software Requirements Specifications • Requirements Reviews • Software design specification document. • Design Reviews • Traceability between requirements & hazards towards their associated mitigations as appropriate and V&V • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification)· Simulated use testing (Validation) <u>Summary of Clinical Tests:</u> The subject of this premarket submission, integrated Innova - s5i system option, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the integrated Innova - s5i system option to be as safe and as effective as the predicate devices, and its performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Faycal Kherra
Regulatory Affairs Leader
GE Healthcare – GE Medical Systems SCS
283, rue de la minière
BUC, 78530
FRANCE

JUL 26 2011

Re: K111209
Trade/Device Name: Integrated Innova-s5i system option
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: April 27, 2011
Received: April 29, 2011

Dear Mr. Kherra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

- 510(k) Number (if known): K 111209
- Device Name: Integrated Innova - s5i system option
- Indications for Use:

The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures.

The Integrated Innova - s5i system option is indicated for use in conjunction with single plane and biplane angiographic X-ray systems.

The Integrated Innova - s5i system option simplifies the clinical workflow associated with the use of Volcano s5i systems by:

(1) automatically synchronizing the patient demographic and medical exam information (patient name, date of birth, etc.) from angiographic X-ray systems with Volcano s5i systems,
(2) providing a remote access to commonly used Volcano s5i system functions from the angiographic X-ray systems user interface,
(3) displaying the Volcano s5i systems output on the monitor display solutions of the angiographic X-ray systems.

Prescription Use X _____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111209